

REMARKS

Status of the Claims and Claims Amendments

As of the recent Office Action, claims 1, 8, 14-16, 18-22 were pending in the application. Claims 14-16 and 18-22 were withdrawn from consideration, and claims 1 and 8 were pending and under prosecution.

Claims 1 and 8 are rejected. Claim 8 is objected to. By way of this response, claim 8 is amended, and claims 23-35 are newly added. Support for the amendments can be found throughout the specification and claims as originally filed. Support for the amendments to claim 8 can be found, for example, at least on page 5, lines 22-35 of the specification as filed, and in Examples 1-3 (pages 9-10). Support for new claims 23-26 and 30-33 can be found, for example, at least on page 4, lines 11-15, and Example 3, page 10 of the specification as filed. Support for new claims 27-29 and 34 and 35 can be found, for example, at least on page 4, line 33 through line 35 of page 5 and Example 4 (pages 10-11) of the specification as filed. The amendments to claim 8 and new claims 23-36 thus add no new matter, and their entry is respectfully requested.

Upon entry of the amendment, claims 1, 8, 14-16, and 18-35 will be pending and claims 1, 8, and 23-35 will be under prosecution, with claims 1 and 8 being the independent claims.

The foregoing amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Applicant reserves the right to pursue the subject matter of the canceled claims in this or any other appropriate patent application.

Objection to Claim 8

Claim 8 is objected to based on the misspelling of “*albicans*” in claim 8. An appropriate correction has been made and, therefore, withdrawal of this objection is respectfully requested.

Rejection Under 35 U.S.C. 112, First Paragraph – Enablement

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection. The legal test for whether a patent application complies with the requirements of 35 U.S.C. § 112, first paragraph as regards to enablement is whether one of ordinary skill in the art would be able to practice the invention as presently claimed without *undue experimentation*. According to the Federal Circuit, the legal standard is that enablement is not precluded by the necessity of some experimentation such as routine screening. *In re: Wands*, 858 F.2d 731, 735-740 (Fed. Cir. 1988).

The Office Action maintains that CCA1 is one of several essential proteins for the *Candida albicans* species (citing *Song et al., Microbiology* (2003), 149:219-259). The Office Action states that based on the specification, one of ordinary skill in the art allegedly cannot determine that any negative effect on growth or viability seen in a *Candida albicans* cell is due to impairment of CCA1 by the candidate compound, and that because of this, a candidate compound may inhibit growth without impairing CCA1 activity.

Applicants assert however, that one of ordinary skill in the art, on reading the application, would readily appreciate that the assay for CCA1 activity that is fully described in Example 3, using CCA1 protein produced and purified as taught in Examples 1 and 2 of the specification, would readily allow one to determine whether a compound tested for its effect on growth or viability of cells expressing *Candida albicans* CCA1 was an inhibitor of CCA1.

Applicants respectfully assert that, with the teachings provided in the present application and knowledge generally known and available in the art, one of ordinary skill in the art would know how to determine the effect of a test compound tested for its effects on cell growth and viability on CCA1 activity.

For at least the foregoing reasons, Applicant asserts that claim 8 is supported by enabling disclosure and is in condition for allowance. Withdrawal of this rejection is therefore respectfully requested.

Rejection Under 35 U.S.C. 102(e)

Claim 1 is rejected under 35 U.S.C. 102(e) as allegedly being anticipated by US 6,747,137 B1 published June 8, 2004, filed February 12, 1999 (“Weinstock *et al.*”). Applicants respectfully traverse this rejection. To anticipate a claim, a reference must teach each and every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631(Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Claim 1 sets forth a method of screening or testing for candidate anti-fungal compounds that impair CCA1 activity. Step d) of the claim recites: “d) determining the ability of the candidate compound to inhibit CCA1 activity”. The Office Action alleges that Weinstock *et al.* teaches a method of screening test compounds for the ability to inhibit CCA1 activity comprising providing a *Candida albicans* target sequence (citing table 2, columns 587 and 588 contig3807), and contacting a test compound with the CCA1 target sequence to determine whether the compound inhibits the activity of the CCA1 protein (citing column 10, lines 46-47). For at least the following reasons, Applicant respectfully disagrees.

Weinstock *et al.* disclose a method for screening test compounds for anti-fungal activity by selecting an essential fungal specific sequence and testing which compounds bind to it (column 10, lines 46-47 of Weinstock *et al.*). However, Weinstock *et al.* does not disclose the CCA1 gene from *Candida albicans* as an essential gene. Thus the CCA1 nucleic acid sequence provided in an extensive list of open reading frames in Weinstock *et al.* does not qualify, according to the teachings of Weinstock *et al.*, as a target sequence to be assayed for anti-fungal activity.

Further, claim 1 of the pending application specifies that the CCA1 protein from the *Candida albicans* species is contacted with one or more candidate compounds to determine the ability of the candidate compound to inhibit CCA1 activity. Weinstock *et al.*, does not make any mention of CCA1 activity, much less disclose any assays for CCA1 activity, and therefore, Applicant respectfully asserts the requirements for anticipation are not met for pending claim 1.

In light of the arguments set forth above, Applicant respectfully asserts that pending claim 1 is in condition for allowance, and respectfully request that the rejection under 35 U.S.C. 102(e) be removed.


CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that claims 1 and 8, and new claims 23-32, are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned at (858) 350-2319 with any questions or to otherwise expedite prosecution.

Respectfully submitted,
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